ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT
Maysulprim solution for use in drinking water/milk

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each ml contains:
Active substances:
Sulfadiazine ... . 83,35 mg
Trimethoprim ... 16,65 mg

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Solution for use in drinking water/milk
Yellow solution

4. CLINICAL PARTICULARS

4.1 Target species
Calves, lambs, pigs, rabbits and poultry.

4.2 Indications for use, specifying the target species
In calves, lambs, swine, rabbits and poultry:
For the treatment and metaphylaxis of respiratory and digestive diseases caused by microorganisms susceptible to sulfadiazine and trimethoprim association.

4.3 Contraindications
Do not use in case of hypersensitivity to the active substances or any of the excipients
Do not use in animals with severe renal or hepatic impairment.

4.4 Special warnings for each target species
None.
See section 4.11

4.5 Special precautions for use
Special precautions for use in animals
Official, national and regional antimicrobial policies should be taken into account when this veterinary medicinal product is used.
Wherever possible, the use of this veterinary medicinal product should be only based on susceptibility testing.
Use of the veterinary medicinal product deviating from the instructions in the SPC may increase the risk of development and selection of resistant bacteria to the sulfadiazine and trimethoprim and may decrease the effectiveness of treatment with sulphonamides and diaminopyrimidines due to the potential for cross-resistance.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
This product contains sulfadiazine, trimethoprim and macrogol, which can cause allergic reactions in some people. Hypersensitivity to sulphonamides may lead to cross reactions with other antibiotics. Allergic reactions to these substances may occasionally be serious.

People with known hypersensitivity (allergy) to sulphonamides, trimethoprim or macrogol should avoid contact with the veterinary medicinal product.

This veterinary medicinal product may cause skin or eye irritation. During the preparation and administration of medicated drinking water, skin and eyes contact has to be avoided. Wear personal protective equipment consisting in waterproof gloves and safety glasses when handling the veterinary medicinal product. In case of contact with the eyes or skin, wash the affected area with plenty of water, and if skin rash occurs, seek medical advice and show the package leaflet or the label to the physician.

This veterinary medicinal product may be harmful if ingested. Do not smoke, eat or drink while handling the veterinary medicinal product. In case of accidental ingestion, seek medical advice and show the package leaflet or the label to the physician.

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None known.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Teratogenic and foetotoxic effects have been observed in laboratory animals at the above recommended therapeutic doses.

The use is not recommended during pregnancy and lactation.

Do not use in birds in lay and within 4 weeks before the onset star of the laying period.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

In drinking water/milk use.

In calves and lambs:

12.5 mg of sulfadiazine and 2.5 mg of trimethoprim per kg bodyweight every 12 hours for 4 to 7 consecutive days, orally, corresponding to 1, 5 ml of solution per 10 kg of live weight every 12 hours for 4 to 7 consecutive days, diluted in drinking water or milk.

In pigs, rabbits and poultry:

25 mg of sulfadiazine and 5 mg of trimethoprim per kg body weight per day for 4 to 7 days consecutive doses, corresponding to 3 ml solution per 10 kg live weight per day in continuous for 4 to 7 consecutive days, to be diluted in drinking water or milk.

The amount of drinking water or milk consumed by animals depends on their condition physiological and clinical.

In order to obtain the recommended dosage, the concentration of sulfadiazine and in trimethoprim should be adjusted accordingly.

To ensure a correct dosage and avoid underdosing, mean body weights in the group of animals and daily water consumption should be determined as accurately as possible.

The medicated drinking water should be the sole source of drinking water for the treatment duration. Any medicated water which is not consumed within 24 hours should be discarded.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary
None known

4.11 Withdrawal period(s)
Meat and offal: 12 days
Eggs: Not for use in birds producing or intended to produce eggs for human consumption. Do not use within 4 weeks of onset the start of the laying period".

5. PHARMACOLOGICAL PROPERTIES
Pharmacotherapeutic group: anti-infectives for systemic use.
ATC vet code: QJ01EW10.

5.1 Pharmacodynamic properties
Sulfadiazine is a long-acting sulphonamide with a broad spectrum of activity. It is microbiologically active against Gram-positive and Gram-negative bacteria.
Trimethoprim belongs to the diaminopyrimidine family. It is active against *streptococci* and most Gram-negative bacteria.
In combination, these two active ingredients are synergistic. Sulfadiazine is potentiated by diaminopyrimidine, trimethoprim. The combination of these two active ingredients allows blocking sequential biosynthesis of folic acid. These two substances act sequentially on the synthetic route of tetrahydrofolic acid: the sulfonamide by inhibiting the incorporation of acid para aminobenzoic acid in folic acid, trimethoprim specifically inhibiting dehydrofolate microbial reductase. The theoretical spectrum of activity extends to both Gram-positive germs (*Staphylococcus, Usteria* ...) and Gram-negative organisms (*Escherichia coli, Salmonella, Proteus, Enterobacter, Bordetella* ...).

5.2 Pharmacokinetic particulars
Sulfadiazine is considered a semi-retarded sulphonamide with a fairly long persistence of plasma levels. Its binding to plasma proteins is important. The distribution is good in most tissues and organs.
Trimethoprim is rapidly absorbed after oral administration. It is widely distributed in the body.
Both active ingredients are partially metabolized in the liver. Their excretion is essentially renal.

5.3 Environmental Properties
Sulfadiazine and Trimethoprim are persistent in soil
Sulfadiazine is known to be toxic to terrestrial plants and for groundwater biota.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Macrogol 200
Sodium hydroxide solution *for pH adjustment*
Purified water

6.2 Major incompatibilities
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf life
Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life after first opening the immediate packaging: 3 months
Shelf life after dilution in water according to directions: 24 hours
Shelf life after dilution in milk according to directions: use immediately

6.4. Special precautions for storage
This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

Bottle of high density polyethylene (HDPE) with HDPE cap, including an induction seal liner made of Alu/PET/LDPE.

Pack sizes:
Bottle of 1 L
Bottle of 5 L

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

Sulfadiazine is known to be hazardous to terrestrial plants and cyanobacteria. Do not contaminate surface waters or ditches with product or used container.

7. MARKETING AUTHORISATION HOLDER

Laboratorios Maymó, S.A
Vía Augusta, 302
08017 Barcelona
Spain

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE